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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/519,076	03/06/2000	Lawrence Salkoff	8512-00130US	8507

20350            7590            09/10/2002

TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

[REDACTED] EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
1646	//

DATE MAILED: 09/10/2002      //

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/519,076</b>	Applicant(s) <b>Salkoff et al</b>
	Examiner <b>Nirmal S. Basi</b>	Art Unit <b>1646</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on Jun 4, 2002
  - 2a)  This action is FINAL.      2b)  This action is non-final.
  - 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- Disposition of Claims**
- 4)  Claim(s) 1-16, 22-44, 47, 49-52, and 54-56 is/are pending in the application.
  - 4a) Of the above, claim(s) 1-16 and 22-44 is/are withdrawn from consideration.
  - 5)  Claim(s) \_\_\_\_\_ is/are allowed.
  - 6)  Claim(s) 47, 49-52, and 54-56 is/are rejected.
  - 7)  Claim(s) \_\_\_\_\_ is/are objected to.
  - 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Amendment filed 6/14/02 has been entered.

Applicant has amended claims 47 and 52, canceled claims 17, 19, 21, 45, 46, 48 and 53.

Claims 17, 19, 21, 45, 46, 48 and 53 will be examined as they encompass the elected Group III,  
5 pertaining to purified polypeptide comprising amino acid sequence of SEQ ID NO:16, being encoded  
by the nucleic acid of SEQ ID NO:17. Claims 47, 49, 52 and 54 contain non elected inventions.  
Applicant must amend the claims to remove reference to non-elected invention.

#### **Claim Rejection, 35 U.S.C. 112, second paragraph**

2. Claims 47, 49-52, 54-56 remain rejected, for reasons of record in paper number 7, under 35  
10 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly  
claim the subject matter which applicant regards as the invention.

Claims 50 and 55 remain indefinite because the method of determining the molecular weight  
has not been identified. Applicant argues measuring the molecular weight is well known in the art  
and one of skill would understand how to determine the molecular weight. Applicants arguments  
15 have been fully considered but known found persuasive. Examiner agrees that measuring the  
molecular weight is well known in the art and one of skill would understand how to determine the  
molecular weight. A value for the molecular weight is entirely dependent upon the method by which  
it is determined and differs with different methods (e.g. denaturing gel, native gel, calculated from  
amino acid sequence, gel filtration etc.). The same protein may give different molecular weights

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dependent on the method used to do the determination. Recitation of a molecular value without reference to the method by which it was measured is indefinite.

Claims 47 and 52 remain indefinite because it is not clear what activity is increased, so as to allow the metes and bounds of the claims to be determined. Applicant argues the terms "activity" and "current amplitude" are used interchangeably. Applicants arguments have been fully considered but not found persuasive. The specification does not disclose that both terms mean the same thing and are used interchangeably.

Claims 47 and 52 are indefinite because it is not clear what is "channel activity above approximately intracellular pH of 7.1". Applicant argues the word approximately has been deleted from the claims. Applicants arguments have been fully considered but not found persuasive. The claims still contain the indefinite language. Instant invention is a pH sensitive potassium channel, its sensitivity to pH fluctuations and the conductance measured under specific conditions determines the metes and bounds of the group of polypeptides that would meet the limitations of the claim. The pH and conductance are critical features of the invention and dictate which polypeptide are encompassed by the claim the metes and bounds of the claims cannot be determined without the disclosure of the metes and bounds of "approximately". It is not clear when is the intracellular pH is approximately 7.1 as compared to when intracellular pH is not approximately 7.1.

Claims 49, 51, 52, 54 and 56 are indefinite for depending on an indefinite base claim or intermediate claim and fail to resolve the issues raised above.

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***Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph***

The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to  
5 the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 47, 50, 51, 52, 54-56 remain rejected, for reasons of record in paper number 7, under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial 15 asserted utility or a well established utility. Applicant arguments and the Declaration of Dr. Timothy Jegla have been fully considered but not found persuasive. Applicant and Dr. Timothy Jegla argue that intracellular pH has a profound effect on the viability of mammalian sperm, alkaline pH is necessary for sperm capacitation and acrosome reaction, sperm capacitation is accompanied by increase in potassium permeability that hyperpolarizes the membrane, and conclude since Slo3 is 20 highly expressed in sperm and is activated by alkalinization the Slo3 channel plays an important role in sperm capacitation and is an excellent target for candidate compounds that modulate sperm function. Applicants arguments have been fully considered but not found persuasive. The potassium channel of instant invention was isolated from testis. The specification does not disclose that the claimed invention was isolated from spremacocytes as stated by Applicant. Until a showing that the

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claimed invention was known to be predominantly expressed in the spermatocytes the rejection of record in paper number 7 is maintained.

**Claim Rejection, 35 U.S.C. 112, first paragraph**

5       4.      Claims 47, 50, 51, 52, 54-56 also remain rejected, for reasons of record in paper number 7, under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Since neither the specification nor the art of record disclose any activities or properties that would 10 constitute a “real world” context of use for the polypeptides of instant invention, further experimentation is necessary to attribute a utility to the claimed polynucleotides.

The specification does not disclose the special technical feature of the invention that is required for activity . Applicant has not disclosed how to use the variant channel proteins which may have unit conductance of 80-120 ps, some structural similarity to Slo3 of SEQ ID NO:16, but be 15 functionally different.

Due to the large quantity of experimentation necessary to identify and purify active proteins encompassed by claims reciting hybridization, the lack of direction/guidance presented in the specification regarding the identification, purification, isolation and characterization of said polypeptides, the unpredictability of the effects of mutation on the structure and function of proteins

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(since mutations of SEQ ID NO:16, are also encompassed by the claim), undue experimentation would be required of the skilled artisan to make or use the claimed invention.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be  
10 calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### **Advisory Information**

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

20 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi  
5 Art Unit 1646  
September 9, 2002

*michael d. pak*  
MICHAEL PAK  
PRIMARY EXAMINER